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VIA E-FILING & HAND DELIVERY
The Honorable Sherry R. Fallon
844 N. King Street, Room 6100, Unit 14
Wilmington, Delaware 19801-3555

Re: *AbbVie Inc., et al. v. Amgen Inc., et al.*, C.A. No. 16-666-SLR

Dear Judge Fallon:

The three disputes regarding the protective order arise from Amgen's desire to place overly burdensome and unnecessary restrictions on individuals bound by its terms.

First, Amgen proposes a regulatory bar that would prohibit any substantive involvement in citizen petitions to the FDA. D.I. 36 ¶ 36. That proposal should be denied. Amgen has the burden to show good cause to institute a bar. *In re Deutsche Bank Trust Co. Americas*, 605 F.3d 1373, 1378 (Fed. Cir. 2010). But it cannot because agreed-upon provisions of the order make such a bar excessive. The parties already agree that confidential information can be used "*only* for purposes of this Litigation and future United States patent infringement litigation between the Parties." D.I. 36 ¶ 27 (emphasis added). This restriction expressly prohibits using confidential information for purposes of "any petitioning, counseling, litigation, or other work involving the [FDA]" and "any other … governmental or regulatory purpose, domestic or foreign." *Id.*

This Court has repeatedly rejected bars such as the one Amgen proposes. *E.g.*, Ex. 1, *Cephalon, Inc. v. Impax Labs., Inc.*, No. 11-1152-SLR, D.I. 56 (D. Del. June 29, 2012) (discussing Cephalon's prior citizen petitions and denying Impax's request for a bar, because "I have rejected similar requests in the past, finding no support for the proposition that 'the risk of inadvertent disclosure to the FDA in the ANDA context warrants the substantial burden such a bar would impose'") *mandamus denied*, 495 F. App'x 82 (Fed. Cir. 2012); Ex. 2, *Mayne Pharma Int'l Pty Ltd. v. Merck & Co., Inc.*, No. 15-438-LPS, D.I. 47 at 13:20-23 (D. Del. Mar. 4, 2016) ("[A]ll of the examples that the [proponent of the bar] points to for what it is concerned with … are already prohibited under the agreed-upon portions of the protective order"). Moreover, the bar would impose a substantial burden. Ex. 3, *Eurand, Inc. v. Mylan Pharms., Inc.*, No. 08-889-SLR, D.I. 71 (D. Del. June 23, 2009) (rejecting regulatory bar). Unsurprisingly, then, at least within the Third Circuit there appears to be no "example of an FDA bar being disputed and then a court resolving that dispute in favor of the FDA bar." Ex. 2, *Mayne*, at 14:14-16.

Second, the parties dispute whether non-attorneys should be subject to the bars. D.I. 36 ¶¶ 35-37. Amgen insists that these bars should apply not only to lawyers, but also to outside experts and their support personnel, interpreters, court reporters, videographers, vendors, and even court personnel. *Id.*; *see also id.* ¶ 31(c), (f)-(j).

Amgen cannot show good cause for such broad and imposing bars. *Deutsche Bank*, 605 F.3d at 1378. To do so, Amgen would need to show that each category of individual barred "reasonably reflect[s] the risk presented by the disclosure of proprietary competitive

information." *Id.* at 1381; *see id.* at 1378 (bar proponent must show "unacceptable opportunity for inadvertent disclosure"). As the Federal Circuit has recognized in the prosecution-bar context, however, bars are often unwarranted even with regard to certain *attorneys*, such as those whose "duties … involve little more than reporting office actions or filing ancillary paper work" or "high-altitude oversight … , such as staffing projects or coordinating client meetings, but have no significant role in crafting the content of patent applications or advising clients on the direction to take their portfolios." *Id.* at 1379-80. With the possible exception of experts, none of the individuals Amgen seeks to bar are any less "remote" from "competitive decisionmaking" than such attorneys. *Id.* at 1380. These individuals should also be exempt.

The prosecution bar on experts is particularly troublesome, because they have no involvement with regard to staking out claim scope, but can be called upon to provide much needed subject-matter expertise to support claims drafted by others. There is almost no risk of inadvertent disclosure, yet they would be limited by the prosecution bar if subject to it since it prohibits "substantively … assisting in obtaining a patent." D.I. 36 ¶ 14, ¶ 35(a). Furthermore, the competitive-decision making bar becomes ambiguous when applied to medical experts who prescribe adalimumab. *Id.* ¶ 37. And the protective order already provides Amgen a mechanism to object should any particular expert pose a particular problem. *Id.* ¶ 33. There is no reason to categorically bar experts from all possible prosecution-related and competitive-decision making activity.

Third, the parties dispute whether the bars (prosecution, competitive decision-making, or regulatory, if ordered) can expire one year after an individual withdraws from representing a party in the litigation and destroys any confidential information. D.I. 36 ¶ 38. AbbVie believes that expiration of the bars one year after withdrawal is necessary. In the past, Amgen has as well. *E.g.*, Ex. 4, *Amgen Inc., v. Hospira, Inc.*, No. 15-00839-RGA, D.I. 31 ¶ 27(b) (D. Del. Mar. 18, 2016) (agreed-upon order states "[t]he [prosecution, regulatory, and competitive-decisionmaking bars] described in this Paragraph . . . shall end the earlier of (i) one (1) year after final termination of this Litigation or (ii) one (1) year after a Designated Inside Counsel withdraws from representing a Party in this Litigation.").

Amgen cannot show good cause why the same expiration provision should not apply here. *Deutsche Bank*, 605 F.3d at 1378. As Amgen's prior practice indicates, one year is a sufficiently long period to protect against the risk of inadvertent disclosure or competitive use. *Id.* at 1380. Moreover, the benefit of any further protection must be balanced against the hardship it would impose. *Id.* That hardship would be significant: AbbVie employees well-removed from any Amgen confidential information would be restricted from activities related to adalimumab, the company's largest product, negatively impacting their progression opportunities.

In the end of the day, *everyone* who signs the protective order will be precluded from using confidential information for an improper purpose, irrespective of any bars. Imposing arbitrary and overly-burdensome bars would serve no useful purpose, and would only serve to unnecessarily discourage people from assisting with the case, or needlessly restrict the employment and consulting opportunities of those who do.

Respectfully submitted,

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cc: All Counsel of Record